



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,243	01/16/2002	Stephen Giovannoni	245-62107	6181

7590 06/30/2004

KLARQUIST SPARKMAN, LLP
Suite 1600
One World Trade Center
121 S.W. Salmon Street
Portland, OR 97204

EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT PAPER NUMBER

1637

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,243

Applicant(s)

GIOVANNONI ET AL.

Examiner

Alexander H. Spiegler

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-21 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-21 and 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/16/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1637

DETAILED ACTION

Status of the Application

1. Currently, claims 1-8, 11-21, and 23-30 are pending are rejected herein. This action is made NON-FINAL.

Sequence Notes

2. The Sequence Listing filed in this application complies with the requirements of 37 CFR 1.821-1.825 and has been entered.

Information Disclosure Statement

3. The information disclosure statement filed on January 16, 2002 complies with CFR 1.97, 1.98, and M.P.E.P. 609, and has been considered (see enclosed, signed PTO-1449).

Claim Objections

4. Claim 1 is objected to because the claim does not include a “;” after the recitation of “hybridization of a probe to a nucleic acid molecule of the microorganism”.
Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1637

6. Claims 1-8, 11-21, and 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 and 30 have been amended to recite, “wherein growth of the microorganism comprises an increase in the number of microorganisms in the compartment to no more than about 5×10^4 cells/milliliter”. However it is not clear where there is support for this recitation. It is noted that on page 23, Example 4, the specification teaches that 200 ul of culture was taken from each well of a microtiter plate and placed in a vacuum filtration manifold device, and later, typically, the sectors of an array “contained 100 to 10,000 cells, although in some cases only a few (but usually > 10) cells might be counted.” This passage does not support the recitation of “wherein growth of the microorganism comprises an increase in the number of microorganisms in the compartment to no more than about 5×10^4 cells/milliliter”.

7. Claims 1-8, 11-21, and 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1 and 30 are drawn to methods comprising gathering a microorganism that “has not been cultured using standard culturing techniques”.

35 U.S.C. § 112, requires, *inter alia*, that a patent specification contain a written description of the invention and the manner and process of making and using it “...in such full clear and concise terms as to enable one skilled in the art... to make and use” the invention. While it is well settled that a patent application need not teach each possible embodiment of the claimed invention, it is manifestly true that written description cannot be settled by reliance on that which has not been achieved in the art, or that which is not disclosed in the specification. That is, a specification is not considered to satisfy the requirement for an adequate written description if it fails to disclose the specific starting materials or conditions for making the invention. (*Genentech, Inc. v. Novo Nordisk*, 108 F3d. 1361, 42 USPQ2d 100. Fed. Cir. 1997).

Additionally, *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention. The invention is, for purposes of the written description inquiry, *whatever is now claimed* (See page 1117).”

Possession may be shown in many ways. For example, possession may be shown, *inter alia*, by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas, which permit a person skilled in the art to clearly recognize, that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention...

Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that

Art Unit: 1637

distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient...In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention. In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession.”

(Federal Register/Vol. 66, No. 4/Friday, January 5, 2001/Notices; p. 1105-1106).

In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA...’requires a precise definition, such as by structure, formula, chemical name, or physical properties’, not a mere wish or plan for obtaining the claimed chemical invention”.

In the instant case, the specification does not provide an adequate written description of culturing techniques that are not considered to be “standard culturing techniques”. The specification does not demonstrate that Applicants’ were in possession of the claimed invention at the time of filing the instant application. On page 8, under the section titled, “High-throughput culturing”, the specification states, “Procedures for obtaining cultures of cells using culture arrays are disclosed. These procedures can be used to discover new microbial organism that have not been amenable to standard culturing techniques”, however, this passage does not teach

what culturing techniques are not considered to be “standard culturing techniques”.

Furthermore, in Examples 3-4 and in the “High-throughput culturing” section, it appears as if it is the “screening” that is done in a high-throughput manner, not the actual “culturing”. In addition, it is also noted that “high-throughput” is not defined in the specification. Also, the generic statement that defines a genus of culturing techniques by only their functional activity (e.g., not standard culturing techniques) does not provide an adequate written description of the genus. Accordingly, because the specification does not teach that Applicants’ were in possession of the claimed invention, at the time of filing the instant application, the claims lack adequate written description.

8. Claims 1-8, 11-21, and 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

MPEP 2164.01 states:

“Even though the statute does not use the term ‘undue experimentation,’ it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).”

The *Wands* court outlined several factors to be considered in determining whether a disclosure would require undue experimentation:

“They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the

Art Unit: 1637

invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *Id.* at 1404.

In the instant case, the specification does not enable one of skill in the art to make and use the claimed invention for the following reasons:

(1) The quantity of experimentation necessary

In order to practice the invention, the practitioner must gather a microorganism that has not been cultured using “standard culturing techniques”. This would require the skilled artisan to determine what is encompassed by “standard culturing techniques” and gather a microorganism from a source environment, wherein the microorganism has not been cultured using “standard culturing techniques”. The specification does not provide guidance on this issue.

In essence, the experimentation that one skilled in the art would be required to perform is in fact the proposed novelty of the invention. “(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement”. (*Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001).

Therefore, the quantity of experimentation is not only difficult, but also unpredictable.

(2) The amount of direction or guidance presented

The specification provides guidance on general methods of culturing, but does not teach what is considered to be “standard” or not “standard” culturing techniques.

(3) The presence or absence of working examples

One working example is presented which details a specific method of culturing, but does not teach what is considered to be “standard” or not “standard” culturing techniques.

(4) The nature of the invention

The invention is directed to a method of isolating and identifying a microbial species from a source environment.

(5) The state of the prior art

The prior art of Bull et al. (Microbiol. And Molecular Biol. Rev. (2000) 64(3): 573-606) teaches the difficulties of detecting uncultured prokaryotes. In Applicants' declaration, on page 3, the inventors state, "our claimed methods address a long-standing problem inherent in the standard microbiological culturing techniques. This problem is emphasized in Bull et al. (2000)..." Thus, Applicants' acknowledge the difficulties in "standard" culturing techniques, however, they only provide one specific culturing technique in Example 3. This example is not designated as a "non-standard" culturing technique.

(6) The relative skill of those in the art

The level of skill in molecular biology is high, as recognized by Applicants (in their declaration) and in the teachings of Bull (see above).

(7) The predictability or unpredictability of the art

As taught by Bull and emphasized by Applicants' declaration, the art of culturing microorganism using "non-standard" culturing techniques is unpredictable.

(8) The breadth of the claims

The invention is directed to a method of isolating and identifying a microbial species from a source environment, comprising gathering a microorganism that has not been cultured by any "standard culturing technique".

Due to the large quantity of experimentation necessary to determine what is considered to be non-standard culturing techniques, the lack of direction/guidance presented in the

Art Unit: 1637

specification regarding culturing microorganism using non-standard techniques, the complex nature of the invention, the state of the prior art of Bull (see above), the high level of skill of those in the art, the unpredictability of using “non-standard” culturing techniques, and the breadth of the claims which fail to recite limitations as to what is encompassed by “standard culturing techniques”, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Applicants are reminded that the enablement requirement of 35 U.S.C. 112, first paragraph, is separate and distinct from the description requirement. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 112, 2nd Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-8, 11-21, and 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8, 11-21, and 23-30 are indefinite over the recitation of “standard culturing techniques” because it is not clear as to what culturing techniques are considered to be “standard”, and culturing techniques are not considered to be “standard culturing techniques”. For example, the specification does not teach a list of possible culturing techniques that are not considered to be “standard culturing techniques”, and therefore, it is not clear as to what techniques are encompassed within the claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-8, 11-21, 23-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jovanovich (USPN 5,756,304), cited in the IDS, in view of Sosnowski et al. (USPN 6,051,380), cited in the IDS.

Jovanovich teaches a method of screening microorganisms for bioremediation. Specifically, Jovanovich teaches a method a method of isolating a microbial species form a source environment, comprising:

a) gathering from the source environment a sample expected of containing at least one microorganism that has not been cultured using standard culturing techniques;

Art Unit: 1637

b) providing a volume of culture medium to the microorganism in at least one microtiter plate compartment;

c) incubating the microorganism in the medium for a period of time and in an environment sufficient to result in growth of the microorganism if the medium and environment are capable of supporting such growth to produce a culture sample wherein growth of the microorganism comprises an increase in the number of microorganisms in the compartment to “no more than about” 5×10^4 cells/milliliter;

d) detecting growth of the microorganism using an automated detection method that comprises removing a portion of the culture sample and depositing the portion onto a surface, wherein growth of the microorganism indicates that the microbial species has been isolated from the source environment; and

(col. 16, ln. 40 to col. 17, ln. 43, Fig. 3b, and Figure 4).

Javnovich also teaches that the source can be of any biological or environmental sample, such as soil, water, human fluid or tissue (col. 26, ln. 1-18). The reference also teaches that the microorganisms may or may not be previously cultured (col. 26, ln. 19-22).

Janovich does not teach identifying the microbial species, wherein identifying the microorganism includes hybridization of a probe to a nucleic acid molecule of the microorganism; amplification of a nucleic acid molecule of the microorganism; immunodetection of a molecule of the microorganism; sequencing of a nucleic acid molecule of the microorganism; or a combination of two or more thereof.

However, Sosnowski teaches the use of an array (i.e., microtiter plate) for a variety of multi-step and/or multiplex reactions and procedures such as, nucleic acid hybridization,

Art Unit: 1637

amplification, immunodiagnostics, cell sorting, etc. (col. 29, ln. 29-64). The reference also teaches that the array can be two-dimensional (col. 9, ln. 59-65).

One of ordinary skill in the art would have been motivated to use the method of Jovanovich of using a microtiter plate in the detection of a microorganism from a source environment and the method of Sosnowski of nucleic acid hybridization, amplification, immunodiagnostics, cell sorting, etc. on an array, in order to have provided a more thorough detection of a sample from a source environment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Jovanovich and Sosnowski to provide a more effective means of detection of a microorganism.

Applicants Arguments

Applicants argue Javanovich uses the traditional methods of cell detection (e.g., optical density readings), which does not measure cell density below 5×10^4 cells/milliliter. (See page 8 of Applicants' response) Furthermore, Applicants argue the term "isolate" also distinguishes the claimed methods from the methods of Javanovich. (See page 9 of Applicants' response) Applicants also argue that Javanovich screens for a particular type of organism, whereas the instant invention is not so limited. (See page 9 of Applicants' response) Finally, Applicants argue the use of Sosnowski is impermissible hindsight. (See page 11 of Applicants' response)

Response to Applicants Arguments

Applicants' arguments have been considered, but are not persuasive for the following reasons. First, Applicants are arguing limitations that are not present in the claims. Specifically, the claims do not specifically require a detection of below 5×10^4 cells/milliliter. Next, the specification does not define "isolate" to require a differing interpretation of the methods of

Art Unit: 1637

Javanovich as compared to the methods of the claimed invention. Applicants' argue the term "isolate" has a very different meaning in the present invention and that of Javanovich, however, there is no evidence in the record to support this assertion. Next, Applicants' argument with respect to the alleged limited teachings of Jovanovich with regard to selecting a specific type of organism is not persuasive because the instant claims do not preclude the alleged limiting teachings of Jovanovich, since the instant claims have the open claim language of "comprising". In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the teachings of Sosnowski takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure.

14. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jovanovich (USPN 5,756,304), cited in the IDS, in view of Sosnowski et al. (USPN 6,051,380), cited in the IDS, as applied to claims 1-8, 11-21, 23-25 and 27-29 above, and further in view of Hoover et al. (Bacteriocins of Lactic Acid (1993) Academic Press Inc. pages 23-39), cited in the IDS.

The teachings of Jovanovich are presented above. Jovanovich does not teach the addition of a reporter strain to the medium with an unknown sample from nature.

Art Unit: 1637

Hoover et al. teaches screening methods for detecting bacteriocin activity. Specifically, Hoover teaches simultaneous or direct assays, wherein the producer (i.e. sample) and indicator cultures (i.e. reporter strain) are grown concurrently on the same solid media under the same conditions of incubation (pg. 29). Hoover teaches that this method of detection is both efficient and easy to do as deferred assays (pg. 28).

One of ordinary skill in the art would have been motivated to use the method of Jovanovich and Sosnowski of using a microtiter plate in the detection of a microorganism from a source environment and the method of Hoover of culturing a sample from nature and a reporter strain together, in order to provide a more efficient and less-labor intensive method of detection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Jovanovich and Hoover to provide a more effective means of detection.

Applicants Arguments

Applicants argue Hoover does not remedy the alleged deficiencies in Jovanovich.

Response to Applicants Arguments

Applicants argument has been considered, but is not persuasive for the reasons above. (See response to Applicants Arguments for the 103 rejection of Jovanovich in view of Sosnowski).

15. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jovanovich (USPN 5,756,304), cited in the IDS, in view of Sosnowski et al. (USPN 6,051,380), cited in the IDS, as applied to claims 1-8, 11-21, 23-25 and 27-29 above, in view of Glockner et al. (System.

Art Unit: 1637

Appl. Microbiol. (1996) 19: 403-406), and in further view of Amann et al. (J. of Bacteriology (1990) 17292): 762-770).

The teachings of Jovanovich are presented above. Specifically, Jovanovich teaches a method of isolating and detecting a microbial species from a source environment (i.e. sea water) using an invasive method, which requires that a portion of a culture sample be removed and deposited elsewhere. Jovanovich does not teach depositing a portion of culture sample onto a surface using a filtration manifold, and then identifying the microorganism through sequencing the ribosomal RNA of the microbial species.

Glockner et al. teaches that performing fluorescent in situ detection of rRNA, following vacuum filtration, increases the sensitivity of bacterial detection. (See pages 403 and 406).

Furthermore, Amann et al. teaches the comparative sequencing of rRNA, following the hybridization of rRNA to fluorescently labeled probes, in order to confirm the identification of the microorganism. (See abstract and pages 764 and 768).

In view of the teachings of Glockner and Amann, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Jovanovich and Sosnowski so as to have included the steps of vacuum filtration followed by comparative sequencing the rRNA of microbial species, in order to have achieved the benefits of an assay that reduces contamination and allows for identification of the different subtype strains, which can then be comparing to a plurality of other known microorganisms, enabling a comprehensive detection and analysis method.

Art Unit: 1637

Secondary Considerations

Applicants argue that based on the long felt need in the art and unexpectedly superior results, the claimed invention can be distinguished over the prior art.

Response to Secondary Considerations

Applicants' secondary considerations have been considered, but are not persuasive for the following reasons. First, this action contains new rejections the declaration does not address (e.g., 112, 1st and 2nd paragraph rejections). Next, the claimed methods are not drawn to carrying out the specific method steps in which Applicants used to attain the "unexpectedly superior results". Accordingly, while the art and Applicants' declaration point to the long felt need for improved methods of isolating microorganisms, the claims do not clearly reflect the specific method steps required to meet this long felt need.

Art Unit: 1637

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

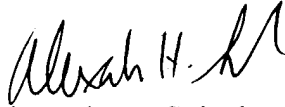
If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

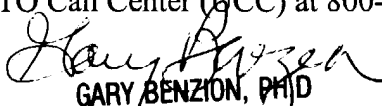
Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (USCC) at 800-786-9199.


Alexander H. Spiegler
June 28, 2004


GARY BENZION, PhD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
6/28/04